MODULAR STERILITY TESTING ISOLATOR

This new Modular Isolator System has been conceived for Lab professionals who require aseptic conditions for sterility testing of pharmaceutical products.
Given the level of aseptic conditions achievable within the system, other processes such as Aseptic Dispensing/Sampling, and Aseptic Product Transfer may be conducted.
The base isolator system is composed of one class A, 4 glove Chamber and one class B Pre-chamber (before sterilization, class A after sterilization). The pre-chamber may be used as a rapid gassing port.
Available upgrades include additional chamber(s), rapid transfer port(s), sterility testing system(s), viable & non-viable counting and an assortment of sensors (which may also be installed at a later date).
The isolator system is equipped with an unidirectional air flow for both chambers with positive pressure with respect to the lab environment. The system is designed to take air from a Class D laboratory or from a HVAC system.
HEPA (H14) unidirectional down flow filters and return filters. Inlet pre-filtration available upon request.
Pressure chamber and inlet/outlet filters are constantly monitored.
All the inflatable and static seals are made of FDA approved White Silicon Bio-Guardian®. This elastomer contains anti bacteria inhibitors that prevent surface growth of micro organisms.
All the view panels are made of 12 mm tempered glass and may be externally laminated with a safety film.
The operator works seated on a predisposed adjustable ergonomic stool supplied with the isolator.

Other key features:

- Fully PLC controlled
- Software GAMP 5 compliant
- Friendly operator interface
- Integrated VHP circuit adaptable to any VHP Generator
- High grade stainless steel 316L internally and 304 externally
- Sliding tray and internal storage systems made of SS 316L.

Designed for FDA 21 CFR Part 11

Gamp 5

COMECER®

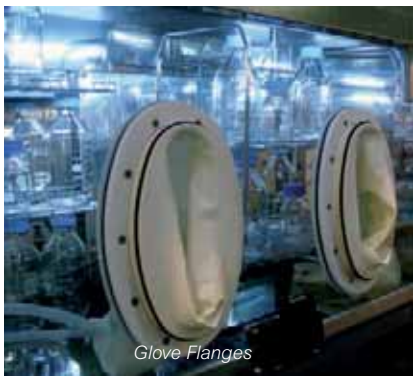
MODULAR STERILITY TESTING ISOLATOR

Technical data	
Stainless steel sheet	Frame structure: AISI 304 Shell structure: AISI 316L
Finishing	External: Scotch - Brite Internal: Mirror - Brite
Boxes' air-tightness in compliance with ISO 10648-2 class 2 - Leak rate per hour	< $2{,}5x10^{-3}$
Weight	1300 Kg
Main chamber air classification	class A
Pre-chamber air classification	class B
Working internal pressure (Main chamber)	50 ÷ 100 Pa
Working internal pressure (Pre-chamber)	25 ÷ 50 Pa
Nr. 3 inlet unidirectional flow filters (Main chamber)*	HEPA H14
Nr. 3 outlet filters (Main chamber)	HEPA H14
Nr. 1 inlet filter (Pre-chamber)*	HEPA H14
Nr. 1 outlet filter (Pre-chamber)	HEPA H14
Overall dimensions (w x d x h)	3002 x 883 x 2163 mm

** Inlet pre-filters available upon request*

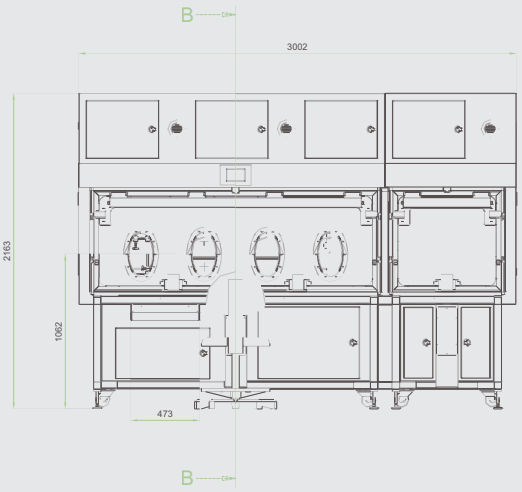
Utilities Requirements	
Power suppy (general)	230V (1Ph+N+PE) 50/60Hz 16A TN-S
Protection degree of the electric system	IP 54
Minimum supply pressure (compressed air/nitrogen)	6 bar

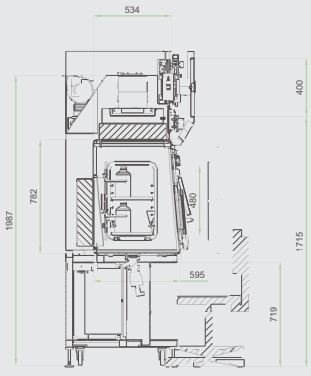
Optional equipments available
Supervisory control and data acquisition (SCADA)
Paperless data recorder
Sterisart NF Sartorius
Steritest™ Equinox Isofit pump Millipore
Particle counter and viable impactor
VHP generator
VHP cycle development and PQ
Integrated VHP circuit
Security sensor for VHP in the Lab environment
Security sensor for VHP low level
Security sensor for VHP high level
Humidity (%rh) & temperature sensor
Flow sensor – anemometer


Glove Flanges


Prechamber


Particle Counter





SECTION B-B

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ISOLATOR FOR API DISPENSING AND ASEPTIC OPERATIONS

The isolator was conceived to guarantee suitable safety and aseptic conditions during preparation of a product containing an active ingredient belonging to category OEB 5 (OEL<0,001 mg/m3). Given the high level of toxicity and the extraordinary integration of the preparation process between the inside and outside of the isolator, a careful study was necessary of all the transfer systems both for solids and liquids as well as the interfaces with all of the equipment involved in the chemical/ physical process, that is: pressurised preparation tanks, peristaltic pumps, thermostatic baths, homogenisers, powder loading system, scales, etc. (instruments provided by the customer).
The isolator is comprised of:

- 1 Dispensing Chamber (in class B) dedicated to dispensing API, connected to two powder loading systems and a preparation tank. Fitted with a reject output liner with welder on board, RTP, SART System and rear view for a view of the laboratory.
- 1 Chamber with dual functionality:
  - Pre-chamber in Negative Pressure: for the initial phase of the process in support of the dispensing chamber.
  - Sterile Chamber: for handling and treatment of the product in liquid phase in aseptic conditions. Fitted with a decontamination system with Vaporised Hydrogen Peroxide (VHP), SART System, RTP, 2 preparation tanks (provided by the customer)

The ventilation system allows independent selection of the following supply modes for each chamber:

- Laboratory air
- Process air
- Nitrogen

Other key features:

- Fully PLC controller
- Software GAMP5 compliant
- Friendly Operator Interface
- LED Lightings
- WIP Circuit
- Double filtration stage H14 inlet and double stage outlet
- Sensors for monitoring the oxygen level
- Humidity and temperature sensors for each chamber
- Circuit with VHP integrated, also usable with other VHP generators.

ISOLATOR FOR API DISPENSING AND ASEPTIC OPERATIONS

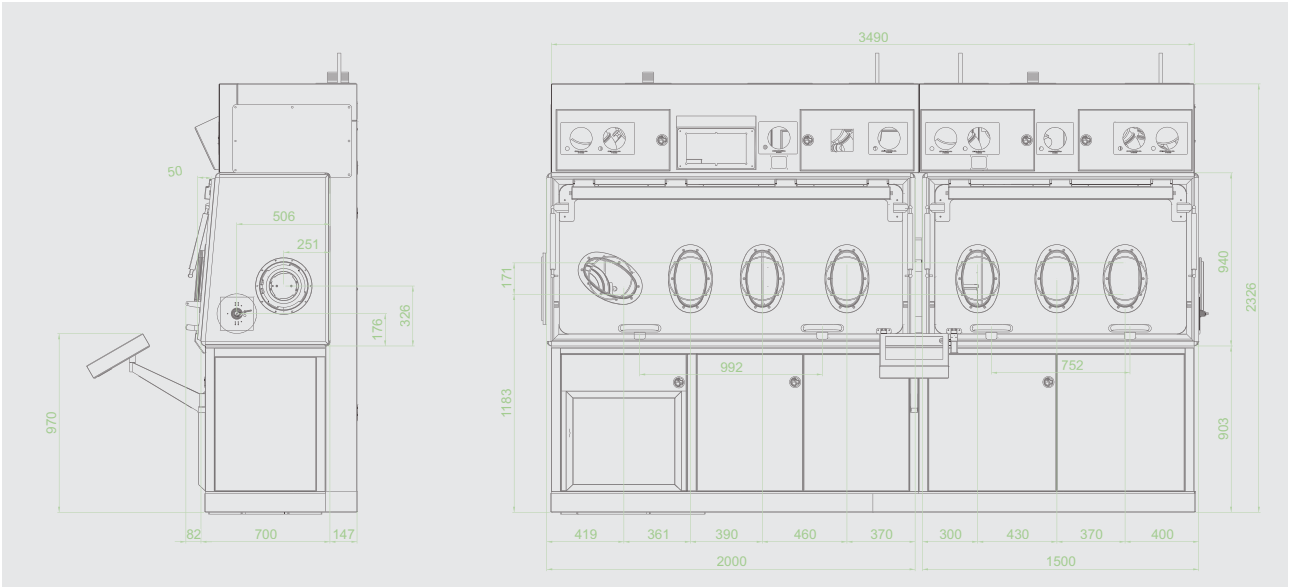
Technical data	
Stainless steel sheet	Frame structure: AISI 304 Shell structure: AISI 316L
Finishing	External: Scotch - Brite Internal: Mirror - Brite
Boxes' air-tightness in compliance with ISO 10648-2 class 2 - Leak rate per hour	< 2,5x10^{-3}
Weight	1300 kg
Main Chamber air classification	Class B
Prechamber air classification	Class A (after sterilisation)
Working internal pressure (main chamber)	-50 ÷ -100 Pa
Working internal pressure (prechamber)	-50 ÷ +100 Pa
Inlet filters	HEPA H14
Outlet filters	HEPA H14
Overall dimensions (w x d x h)	3002 x 883 x 2163 mm

Utilities Requirements	
Power suppy (general)	230V (1Ph+N+PE) 50/60Hz 16A TN-S
Protection degree of the electric system	IP 54
Minimum supply pressure (compressed air/nitrogen)	6 bar


Preparation Tank Integration


Glove Flanges


DPTE Alpha and SART System



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ISOLATOR FOR SAFE HAPI TRANSFER AND DISPENSING

TRANSFER ISOLATOR
The isolator consists of a main chamber and an additional MAL (Material Air Lock) Chamber. The isolator is designed for the secure transfer of HAPI into the appropriate bins:

- The active ingredient is brought into the isolator utilizing a DPTE interface located on the left side of the isolator shell
- The operator weighs the active ingredient, and pours the weighed quantity into a funnel that directs the flow of the ingredient in to a wheeled vessel connected to the isolator shell from the bottom
- A bag-out door is present on the isolator. This bag-out door will be utilized for the expulsion of contaminated bag and cans (primary packaging of active ingredients)

All chambers are equipped with an air inlet filter, two air outlet filters, air inlet and outlet valves and an air extraction fan.
A CIP system is present comprehending spray balls and spray lances, both chambers are equipped with sanitary drain valves.

DISPENSING ISOLATOR
The isolator consists of a left pre-chamber, a main chamber and an exit chamber. The products that have to be dispensed are contained in bins.
The closed bins are brought into the isolator system through the pre-chamber front door and placed on a sliding tray placed between the right pre-chamber and the main chamber.
The bins are then manually moved into the main chamber via a pass-through door. The bin is opened and the material is drawn out from the bin and weighed.
The empty bins are placed on a support structure within the bag-out tube, the maximum capacity of the support structure is 5 stacked bins. These 5 bins will be discharge together in one operation.
The last bin that may contain material will be discharged in a separate operation.
A tri-clamp flange welded to the floor of the main chamber is connected to a Hycoflex system placed on the exit chamber that will furnish the exit point for the weighed material.

All chambers are equipped with an air inlet filter, two air outlet filters, air inlet and outlet valves and an air extraction fan.
Moreover, a CIP system is present for internal washing. The pre-chamber and the main chamber have sanitary drain valves for chamber drainage while the discharge chamber a pneumatic ball valve

Other key features:

- Bottom of chamber sloped to facilitate drainage of wash down fluids
- JUMO manometer for the internal pressure control
- Inverter for ventilation fan speed control
- Automatic valves for air flow interception
- Manual butterfly valve

TRANSFER ISOLATOR

- Polypropylene glove flanges
- Nitrile gloves
- N°1 bag-out tube for bin discharge
- N°1 270-S alpha flang.

DISPENSING ISOLATOR

- Sliding tray
- Bar grills
- Bag-out tube
- Funnel for pouring of material
- 270-S alpha flange
- Polypropylene glove flanges
- Nitrile gloves
- IP65 Illumination units
- Shelf for storage of customer supplied tools

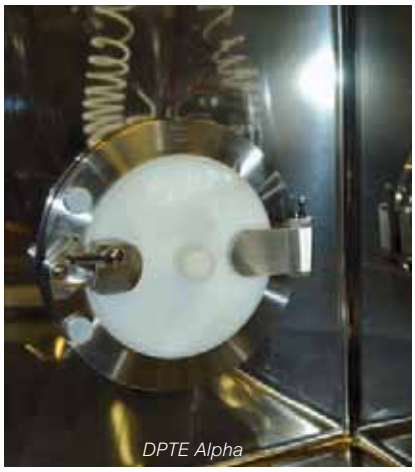
ISOLATOR FOR SAFE HAPI TRANSFER AND DISPENSING

Technical data	
Stainless steel sheet	Support structure: AISI 304 Chambers: AISI 316L
Sheet finish	Support structure: Scotch-Brite Chambers: Mirror Brite
Isolators glass	Tempered with AISI 316L stainless steel frames - ≠ 12 mm
Weight	TRANSFER ISOLATOR: 850 kg DISPENSING ISOLATOR: 1700 kg
Air classification	class ISO5 (B)
Boxes' air-tightness in compliance with ISO 10648-2 class 2 - Leak rate per hour	< $2,5x10^{-3}$
Minimal negative pressure alarm level	-30 ÷ -50 Pa
Inlet air filter type	HEPA H14
Outlet air filters type	HEPA H14

TRANSFER ISOLATOR	
Working Internall negative pressure	-100 Pa
Exhaust air range	70 m^3/h
Overall dimensions	2300 x 1220 x 3170 mm

DISPENSING ISOLATOR	
Working Internall negative pressure (prechamber)	-50 Pa
Working Internall negative pressure (main chamber)	-100 Pa
Working Internall negative pressure (discharge chamber)	-50 Pa
Exhaust air range (prechamber)	50 m^3/h
Exhaust air range (main chamber)	70 m^3/h
Exhaust air range (discharge chamber)	50 m^3/h
Overall dimensions	2747 x 1020 x 3170 mm

Utilities Requirements	
Power suppy (general)	230V (1Ph+N+PE) 50/60Hz 16A TN-S
Protection degree of the electric system	IP 54
Minimum supply pressure (compressed air/nitrogen)	6 bar
WFI	20 l/min (DISPENSING) 18 l/min (TRANSFER)


DPTE Alpha


Integrated Scale


Continuous Liner

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DISPENSING AND WEIGHING ISOLATOR

The isolator was designed to permit the dispensing and weighing activities of micronized highly potent substances (progesterone OEL 0,01 mg/m^3).
This compact isolator is mainly constitute of two chambers:
- Pre chamber: to inlet material
- Main chamber: where to perform dispensing activities

Both the chambers are equipped with an inlet single stage filtration placed inside the box, an outlet first stage filtration also inside and the second one outside. The isolator is also equipped with a special CIP system consisting in spray balls, spray guns and a solvent mixing system. Moreover a Drying In Place has been supplied on board with independent heaters, humidity and temperature probe inside each chamber.
One 380mm diameter continuous liner port has been placed on the side of each chamber to easy exit large drum where the product is stored while only in the main chamber there is an integrated Hycoflex system to take out the dispensed product.

A paperless recorder Eurotherm was also integrated to record all the critical process data like temperature, humidity, chamber pressure.

Other key features:
- Fully PLC controlled
- Software GAMP 5 compliant
- Friendly operator interface
- Sliding Tray
- Pass through door for communication with adjoining chamber.
- 190 mm glove flanges with gloves.
- 270 mm glove flanges with gloves.
- Continuous film port Diam. 380 mm
- rH+T sensor for temperature and humidity internal monitoring.
- Magnahelic Manometers for the internal pressure control
- Inverter for ventilation fan speed control.
- Automatic valves for air flow interception.
- Jumo Manometers to monitor inlet and outlet filters obstruction.

DISPENSING AND WEIGHING ISOLATOR

Technical data	
Stainless steel sheet	Support structure: AISI 304 Chambers: AISI 316L
Sheet finish	Support structure: Scotch-Brite Chambers: Mirror Brite
Isolators glass	Tempered with AISI 316L stainless steel frames - ≠ 12 mm (EN12600)
Weight	1100 Kg
Air classification	class ISO5 (B)
Boxes' air-tightness in compliance with ISO 10648-2 class 2 - Leak rate per hour	$< 2{,}5x10^{-3}$
Exhaust air range (prechamber)	50 m^3/h
Exhaust air range (main chamber)	70 m^3/h
Exhaust air range (discharge chamber)	50 m^3/h
Inlet air filter type	HEPA H14
Outlet air filters type	HEPA H14
Working Internall negative pressure	-30 ÷ -50 Pa
Overall dimensions	2576 x 1751 x 2416 mm

Utilities Requirements	
Power suppy (general)	230V (1Ph+N+PE) 50/60Hz 16A TN-S
Protection degree of the electric system	IP 54
Minimum supply pressure (compressed air/nitrogen)	6 bar
WFI	12 l/min


Prechamber Internal View


HEPA H14 Filter and Sprayball


Spraygun

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DISPENSING ISOLATOR (ATEX COMPLIANT CHAMBER)

The isolator is designed to carry out weighing and powder transfer procedures (API) in complete safety. The isolator consists of a chamber equipped with connections for scales and cable runs, with a front wall in glass which can be opened completely.
The chamber is also equipped with two spray balls and two spray guns for perfect cleaning.
The transfer and discharge of materials takes place by means of a DPTE located on the right side of the chamber and a barrier sack with interlocking door located on the operating surface.
Given the large quantity of rejects, the isolator was equipped with an automatic lift trolley which, placed under the barrier sack, allows accumulation of the rejects and therefore easy transport.
The internal work area is classified as ATEX ZONE 22 Ex II3D_/3, therefore a series of upgrades were adopted in the choice of improved solutions to ensure the handling of the highly explosing substances treated there.
The filtration system is comprised of a single inlet stage inside the enclosure and a double output stage (one inside and one outside the enclosure).
The ventilation system has the following modes based on the type of supply: Laboratory air, Process air and Nitrogen.

Other key features:

- Fully PLC controlled
- Software GAMP 5 compliant
- Friendly operator interface
- Sliding Tray
- Oval glove flanges in PVC equipped with gloves in Hypalon.
- DPTE 270-S ALPHA.
- Turbulent air flow with nitrogen/air/ laboratory air
- Dual output air filtration system
- Exhaust system with Ø186mm flange.
- Magnehelic Pressure Gauge to monitor negative internal pressure
- Inverter for air fan speed control.
- Automatic valves (ON/OFF) for air ventilation.
- Oxygen sensor
- Scale with remote panel
- Photohelic Pressure Gauges to monitor clogging conditions of the air filter

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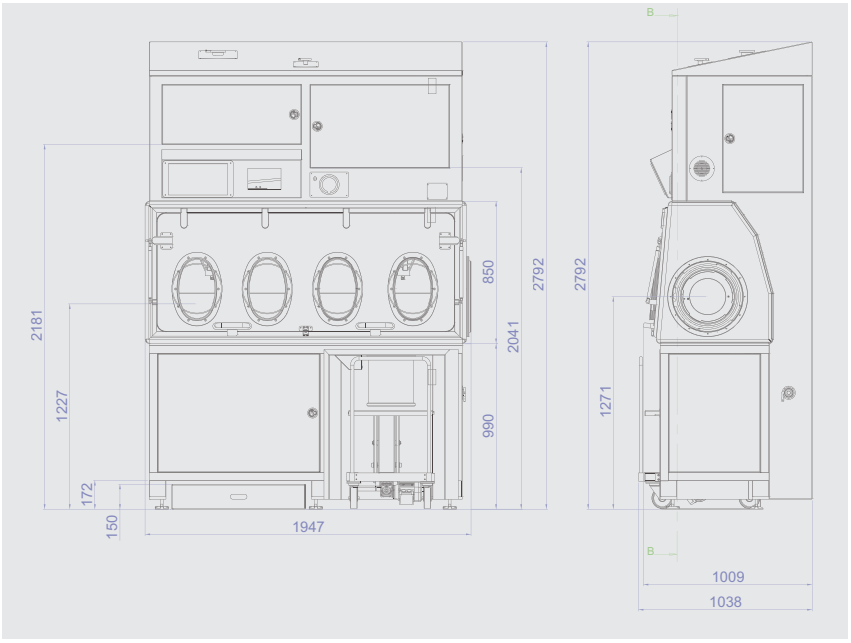
DISPENSING ISOLATOR (ATEX COMPLIANT CHAMBER)

Technical data	
Stainless steel sheet	Support structure: AISI 304 Chambers: AISI 316L
Sheet finish	Support structure: Scotch-Brite Chambers: Mirror Brite
Isolators glass	Tempered with AISI 316L stainless steel frames - ≠ 12 mm (EN12600)
Weight	2500 Kg
Air classification	class ISO5 (B)
Boxes' air-tightness in compliance with ISO 10648-2 class 2 - Leak rate per hour	< 2,5x10^{-3}
Inlet air filter type	HEPA H14
Outlet air filters type	HEPA H14
Working Internall negative pressure	-50 ÷ -100 Pa
Overall dimensions	1947 x 1038 x 2792 mm

Utilities Requirements	
Power suppy (general)	230V (1Ph+N+PE) 50/60Hz 16A TN-S
Protection degree of the electric system	IP 54
Minimum supply pressure (compressed air/nitrogen)	6 bar
WFI	18 l/min




Glove Flanges


Internal View


Electrical Utilities Connection (ATEX Compliant)

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6 STAGES R&D ISOLATOR

- 6 working areas
- Negative pressure in respect with laboratory environment
- High containment suitable for OEB5 products
- Customized project for an increased ergonomic design
- Fully PLC controlled to minimize human errors
- Fully washable with organic solvents to eliminate any trace of product
- Integrated vacuum dryer
- Several integrated utilities such as dry-scroll vacuum pump and pressurized washing liquids (organic solvents)
- Turbulent flow with nitrogen and O_2 monitoring.

COMECER

6 STAGES R&D ISOLATOR


1


2

3


4


5


6

1. *Integrated continuos liner*
2. *Spray gun and RTP port*
3. *Utility: dry scroll vacuum pumps*
4. *Integrated vacuum dryer*
5. *Internal sliding doors with EPDM FDA certified gasket*
6. *Utility: integrated washing circuit*

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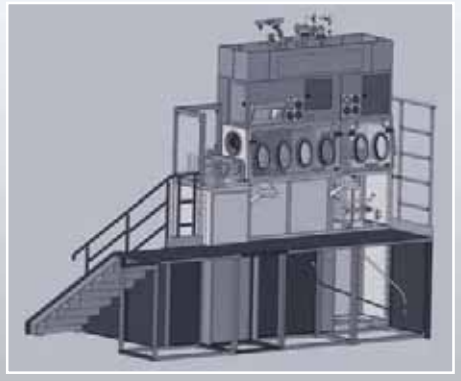
DISPENSING ISOLATOR FOR HAPI (HIGHLY ACTIVE PRODUCT INGREDIENTS)

- Double chamber isolator to weight and dispense HAPI and excipients.
- Fully integrated with:
  bin lifter (to lift excipients bags)
  RTP port to enter with HAPI bags (OEB5)
  bigh containment Twin Valve for dispensing to IBC (HAPI + Excipients)
- Fully PLC controlled, with logical steps to assist the operator through the various process phases
- Turbulent flow with nitrogen and O_2 monitoring
- ATEX Zone 2,22 inside each chamber.



COMECER®

ISOLATOR FOR DISPENSING & MILLING

- Integrated mill
- Integrated scale
- Controlled humidity (% RH)
- Negative pressure
- Turbulent air flow
- Bag-in/Bag-out filter replacement method
- Fully PLC controlled
- Fully washable.

COMECER

ISOLATORS FOR DEDUSTER & METAL CHECK

- Negative pressure with respect to the laboratory environment
- Turbulent air flow
- Bag-in/bag-out filters replacing method
- Fully PLC controlled
- Integrated CIP (clean in place)
- Fully washable.

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ISOLATOR FOR METAL CHECK

- Integrated metalcheck for pills or tablets
- Turbulent air flow
- Fully washable
- Different heights available for cascade installation to different models of dedusting units.

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ISOLATOR FOR COMPACT MIXER-GRANULATOR-DRYER

- Negative pressure with respect to the laboratory environment
- Fully PLC controlled (single PLC for isolator & mixer-granulator-dryer)
- Top-down turbulent air flow
- Pre-chamber for inlet and outlet procedures
- Integrated CIP (clean in place).

COMECER®

MILLING ISOLATOR

- 4 working areas
- Turbulent flow under nitrogen atmosphere
- O_2 monitoring
- Negative pressure with respect to the laboratory environment
- Fully PLC controlled
- Fully washable.

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AGT
AUTOMATIC GLOVE TESTER

This system is used to test glove integrity in conformity with the pressure decay method ISO14644-7 Annex E.5 (test in positive pressure)

- Automatic Leak Tester
- Data record and traceability options
- Touch screen and User Friendly SW
- Integrated oil-free compressed air (Medical Grade)
- Dedicated on board Vacuum Generator
- Easy Start-up, Transfer & Testing.

COMECER®

AGT

Standard features

Automatic Glove Tester: the system is equipped with 1 module to test up to 12 gloves simultaneously following the pressure decay method ISO14644-7 Annex E.5.
Isolator Chamber Leak Tester: the system performs the leak test of an isolator chamber using a dedicated glove flange cover equipped with a differential pressure transmitter and temperature sensor (included in the standard configuration).
Integrated Thermal Printer: (60 mm paper in roll) installed on the machine to provide a written report at the end of each test cycle.
Touch screen: Siemens S7-300 (5,7") and user friendly SW
Flange Covers: oval/circular (to be specified by the customer)

OPTIONS
- The system can be configured to integrity test 4, 8 or 12 gloves
- The system can perform integrity glove test on circular, oval and custom-sizes flanges
- DATA TRACEABILITY (printer, wired or wireless Ethernet connection)
- Performance qualification

HOW IT WORKS
The main unit only needs power supply. Compressed air (medical grade - 0,2µm filtered) for glove inflating is supplied by an oil-free compressor on board.
The operator needs to position a flange cover on top of each flange-glove to be tested and easily secure it trough a push button. The AGT is then ready to perform the integrity glove test or the Isolator Chamber leak test.

BENEFITS
- Easy start up: the system just requires electrical power supply.
- Easy transfer: the system is equipped with 4 wheels.
- Easy interface: thanks to the integrated touch-panel and user friendly software.
- Automatic Glove Integrity Test up to 12 gloves
- Independent inflation of each glove
- Isolator Chamber Leak Test in negative or positive pressure (ISO Standards)
- Dedicated on board compressor and vacuum generator.
- Performance validation

Technical specifications	
Stainless steel grade	AISI 304
Stainless steel finish	Scotch Brite
Weight	100 Kg
Glove test pressure	500 –1000 Pa (as per ISO 14644-7 Annex E.5)
Total dimensions ((w x d x h))	800 x 456 x 1038 mm

Utilities Requirements	
Power suppy (general)	230V (1Ph+N+PE) 50/60Hz 16A TN-S
Protection degree of the electric system	IP 54

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C-RABS FOR CRIMPING MACHINE

The C-RAB has the purpose to keep the crimping machine provided by others under Class A environment and laminar air flow the same time being treated a toxic product, it provides a significant level of containment in case of non-fully stoppered vial, an over-turned and broken vial. It can be classified as a passive RABS since ventilation is directly managed by the facility HVAC system.

The C-RAB, from the process point of view, can be split in three sections.

- SECTION 1: Crimping Cabinet (the part housing the automatic crimping machine);
- SECTION 2: Exit Mouse Hole;
- SECTION 3: Crimp Loading Bin
-

The Crimping Cabinet where the laminar flow is provided is equipped with hinged doors and two continuous liner systems for the rejection and sampling. All the glove flanges have sensors to detect hands insertion during operation.
The exit mouse hole has a turbulent ventilation and independent air supply and return to balance pressure difference between the adjacent environments.
The loading bin is placed on the back of the C-RABS, it is connected with tri-clamp to the crimping cabinet where a pneumatic cylinder actuates the door to let the crimps falling down by gravity into the bowl feeder.
Software GAMP5 compliant is completely integrated in the PC of the crimping machine so that a single HMI is used by the operator.

COMECER®

C-RABS FOR CRIMPING MACHINE

Technical data	
Stainless steel sheet	Frame structure: AISI 304 Shell structure: AISI 316L
Finishing	External: Scotch - Brite Internal: Mirror - Brite
Isolators glass	Tempered with AISI 316L stainless steel frames - ≠ 12 mm
Weight	800 kg
Inlet filters	HEPA H14
Overall dimensions (w x d x h)	2333 x 1511 x 2345 mm

Utilities Requirements	
Power suppy (general)	230V (1Ph+N+PE) 50/60Hz 16A TN-S
Protection degree of the electric system	IP 54
Minimum supply pressure (compressed air/nitrogen)	6 bar


Crimps Load Hopper


Hopper Pneumatic Port (detail)


Hopper Pneumatic Port

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PASSIVE RABS FOR CONTAMINATED MATERIAL HANDLING

This RABS was realised within the revamping of a laboratory in order to obtain a higher grade of protection of the working area already fitted with a simple laminar flow surrounded by two portable straps. The operation allowed a depression level of 20 Pa to be reached.

Other key features:

- Door frames made from AISI 304 steel with lodging for gaskets
- Static gaskets with D profile, made from EPDM and FDA approved for sealing the doors in the closed position
- Frames with fluorescent bulbs to increase internal visibility of the existing hood
- Front panels made with antistatic, 10mm thick panels in Lexan
- Front grille installed in the lower part of each door in order to regulate the air flow coming from the laboratory
- Each door is equipped with two 10" oval gloved flanges and gloves in Hypalon
- All steel components are TIG welded.

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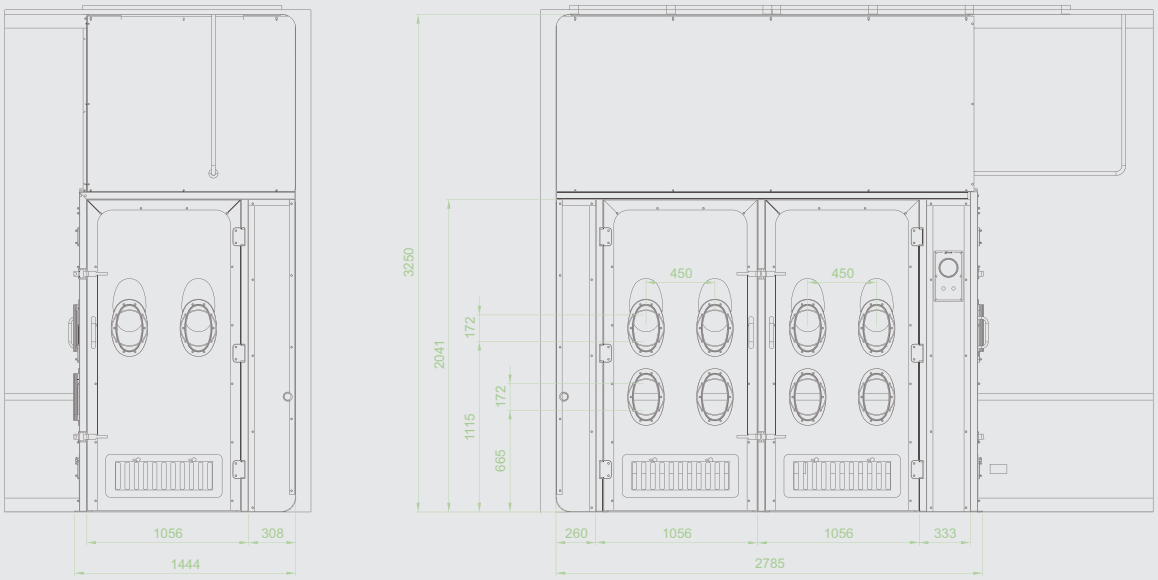
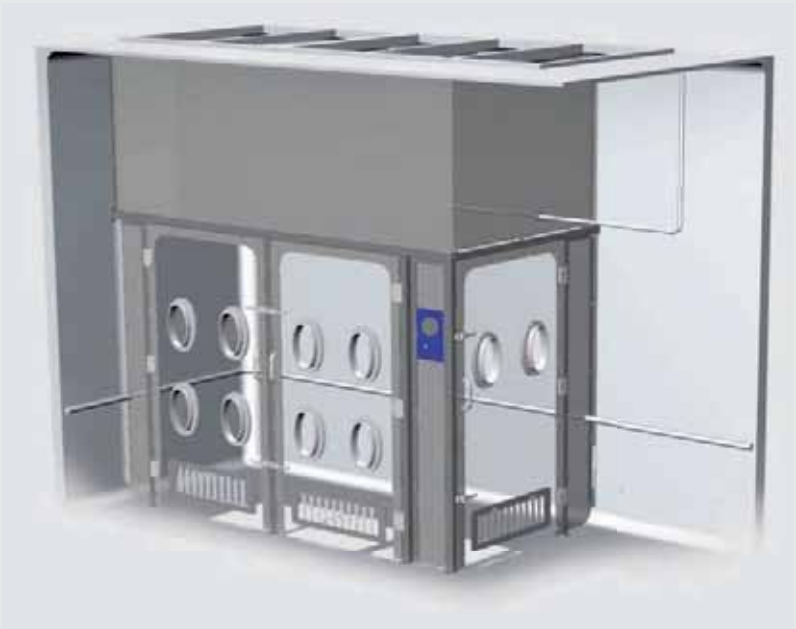
PASSIVE RABS FOR CONTAMINATED MATERIAL HANDLING

Technical data	
Stainless steel sheet	Support structure: AISI 304 Chambers: AISI 316L
Sheet finish	Support structure: Scotch-Brite Chambers: Mirror Brite
Weight	1300 Kg
Overall dimensions (w x d x h)	2785 x 1444 x 2040 mm

Utilities Requirements	
Power suppy (general)	24V
Protection degree of the electric system	IP 54
Minimum supply pressure (compressed air/nitrogen)	6 bar





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MAIN REFERENCES

PFIZER
Ascoli Piceno, Italy

Isolator for Deduster and MetalCheck
Isolators for bottle filling machine
Isolator for operators protection

Illertissen, Germany

(ISPE "Facility of the year Award 2008" Overall Winner)

Isolator for Deduster and MetalCheck
Isolator for PAT procedures

Puurs, Belgium

Isolator for secure Transfer of HAPI
Isolator for Weighing & Dispensing

Belgium

Safety cabinet for API dispensing.

GLAXOSMITHKLINE
Parma, Italy

Isolator for cytotoxic manipulation
Isolator for washing procedures
Isolator for dispensing and milling procedures
Dispensing isolator with high containment split valve (Twin Valve by IMA)
Isolator for tablet testing
Isolator for API dispensing and aseptic operations
Two chambers dispensing isolator for API

Bad Oldesloe, Germany

(now Aspen Pharma)

Dispensing isolator with high containment split valve (Dispensing Workstation by Lobotech and split valve MC200 by Gea-Buck)

Poznan, Poland

Dispensing isolator for soft gel with slurry vessel

TEVA
Santhià, Italy

Isolator for micronizer

Opava, Czech Republic

4 stages Isolator for chemical synthesis process

Debrecen, Hungary

Isolator for HAPI production

PLIVA LACHEMA
Brno, Czech Repubblic

Isolator for aseptic filling line: accumulation table isolator, filling machine isolator, lyo loading/unloading isolator, capping machine isolator

CERBIOS PHARMA
Lugano, Switzerland

Isolator for chemical synthesis process
6 Stages R&D Isolator
Mobile Reactor Isolator. ATEX zone 2,22 (4 units)
Isolator with vacuum dryer. ATEX zone 2,22
Isolator for analytical tests
Isolator for manual packaging

NOVARTIS
Stein, Switzerland

Isolator for Capsule Filling Machine
Isolator RQ100 (tablet tests)

ACTAVIS
Nerviano, Italy, Switzerland

C-RABS for vial filling machine

IBSA
Lugano, Switzerland

Weighing Isolator for API

WYETH
Puerto Rico

Isolator for Deduster and MetalCheck
Isolator RQ100 (tablet tests)

JANSSEN
Latina, Italy

Dispensing isolator

CHUGAI (ROCHE GROUP)
Japan

Isolator for metal-check analysis
Isolator for RQ-100 Tablet Testing

SCHERING
Milano, Italy

Class 10000 isolator

HOFFMAN-LA ROCHE
Switzerland

Isolator for RQ-100 Tablet testing

BRISTOL-MYERS-SQUIBB
Latina, Italy

Isolator for Fractioning

MDS NORDION
Fleurus, Belgio

Screened isolator with laminar flow

BOERINGER MANNHEIM
Italy

Class 100 isolator line

DKFZ
Germany

Laminar flow isolator

ROMACO ZANCHETTA
Lucca, Italy

Isolator for compact mixer-granulator-dryer

ENDURA
Ravenna, Italy

RABS for aseptic filling (Healthcare industry)

GOGLIO
Varese, Italy

3 stages isolator for sterile filling, with on-line VHP sterilization (Food industry)

FARMABIOS
Pavia

Four chambers isolator for filtration process
Three chambers isolator for weighing dissolution
Two chambers isolator for quality control

SYNTECO
Pavia

Three Chambers Isolator for API dispensing with vacuum dryer predisposition

IMA GROUP
Germany

Isolator for RQ100 Tablet Tester

BIOCEN
Cuba

Sterility Testing Isolator

CIDEM
Cuba

Sterility Testing Isolator

PSICOPHARMA
Mexico

Sterility Testing Isolator
PHL Isolator

UNDER CONSTRUCTION

ZENTIVA (SANOFI GROUP)
Romania

Sterility Testing Isolator

CHIESI
Italy

ATEX isolator for compounding

NCPC
China

Sterility Testing Isolator

FDC
India

Automatic Glove Tester (AGT)

ADIMMUNE
Taiwan

Active C-RABS for syringes filling

ELY LILLY
USA

Automatic Glove Tester (AGT)

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COMECER VALIDATIONS
FAT & SAT PROTOCOLS

According to the GMP requirements (Good Manufacturing Requirements), each manufacturer has the task to identify the validation steps which are necessary in order to prove that the critical aspects of his particular operation are under control.

Main steps of Validation:

1. *URS - User Requirement Specification (by User)*
2. *DQ-Design Qualification (standard supply, can be covered in normal design reviews)*
3. *FAT-Factory Acceptance Test (standard supply)*
4. *SAT-Site Acceptance Test (standard supply)*
5. *IQ-Installation Qualification (optional supply)*
6. *OQ-Operation Qualification (optional supply)*
7. *PQ-Performance Qualification (by User).*

Comecer supply FAT (Factory Acceptance Test) validation protocols for every Hot Cell/ Dispensing system/Isolator. Comecer perform SAT (Site Acceptance Test) and supply if requested IQ & OQ protocols (Installation Qualification & Operational Qualification). The validation protocols comply to the following standards:

- ISO 14644 (Clean-rooms and associated controlled Environments)
- ISO 10648 (Containment enclosures)
- EEC-GMP (Good Manufacturing Practice - Annex 1 Manufacture of sterile Medicinal Products)
- PDA -TR Nr 34 (Design and Validation of Isolator Systems for the Manufacturing and Testing of Health Care Products).

FAT (Factory Acceptance Test)

The complete validation test for the equipment will be performed at Comecer's site. The FAT protocol will include the following tests:

1. *Test Instrument Data (Calibration Certificates of the reference instruments)*
2. *System Documentation Verification (documents list for the equipment qualification)*
3. *Construction Design Verification ("As Built drawings and schemes")*
4. *Main Equipment Specification Verification (correspondence with the design)*
5. *Functionality/Interlocks Verification (Mechanical & Software)*
6. *Glove Breach Test (only where gloves provided)*
7. *Unidirectional Air Flow Verification (Smoke pattern test - only with Laminar flow)*
8. *Air Change Rate*
9. *Air Velocity Verification (only with Laminar flow)*
10. *Filter Leakage (Integrity test)*
11. *Leak tightness Test (only if applicable)*
12. *Non Viable Particle Counts (Air classification).*

SAT (Site Acceptance Test)

The SAT will include the following tests:

1. *Finishing Visual check*
2. *Main components visual check*
3. *Internal box pressure and ventilation setting*
4. *Utilities functionality and setting check*
5. *Functionality/Interlocks Verification (Mechanical & Software)*
6. *Hot test for dispensing systems (activity source supplied by Customer)*
7. *Dose calibrator verification (activity source supplied by Customer)*
8. *Safety devices and interlocks check*
9. *Operator's training*
10. *Delivery of the performed FAT protocol and documentation package including:*
    - Performed FAT Protocol
    - Maintenance and User's manual
    - Recommended spare parts list
    - Certificate of compliance
    - As built technical drawings (electrical, mechanical, pneumatic & process schemes)
    - Materials certificates/data sheets
    - Main equipments data sheets
    - Instruments calibration certificates
    - Welding Processes qualification.

Optional: IQ & OQ (Installation Qualification & Operational Qualification)

If requested, as an optional service , Comecer can perform IQ-OQ validation at customer's site. The IQ-OQ validation will be performed by qualified technicians (Comecer Validation Dept.) using calibrated instruments and the protocol will include the complete tests list as performed during the FAT, repeated again at customer's site.


Laminar Flow Air Velocity


Glove Breach test


Filter Leakage


Unidirectional Air Flow Verification (Smoke pattern test)


Leak tightness test


Particle Counting Test (Air classification)

COMECER VALIDATIONS FAT & SAT PROTOCOLS

Welding qualification

The stainless steel welding is the more relevant production process for Comecer. This process and the use of high quality materials like stainless steel AISI 316L with mirror-brite finish grade, allow Comecer to qualify its products in the top standard in the field of isolation technology. All the boxes used for containment are welded with TIG method (Tungsten Inert Gas).
The welding are made from operators that follow processes certified from the notify institution RINA, in compliance with the following norms:

EN ISO 15614-1

(PQR) Procedure Qualification Record

EN 15609-1

(WPS) Welding Procedure Specification

EN 287-1

(WPQ) Welder Performance Qualification

EN 1418

Welding operator approval certificate

All the welding qualifications are also in agreement with **the section IX of ASME Code.**

The weldings are tested by Comecer qualified operators for Penetrating Liquid Examination in according with SNT-TC-1A level II and following the specifications of the ASME rules.

Software / Hardware

Optional Requirement for Software/Hardware Control System

GAMP5 (Guide for Validation of Automated Systems)

The automation compliance to GAMP5 is autocertified by Comecer following a development sequence of the project called “Life cycle“. This autocertification is done by preparing the following documents, that describe the functional charateristic of Hardware/Software and their test validation:
- FDS (Functional Design Specification)
- HDS (Hardware Design Specification)
- STS (Software Test Specifications)
- HTS (Hardware Test Specifications)
- Change Control.

CFR21 part11 (Electronic records; electronic signatures)

The compliance of software to the regulation CFR21 part11 is autocertified by Comecer following a documented analysis of the regulation requirements; Comecer describes how this requirements are applied in software development. Also the requirements of CFR21 part11 are validated with a test protocol (STS Software Test Specifications).